

November 18, 2020

Ms. Ingrid Feustel
Chemical Control Division
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RE: Small Entity Representative Pre-Panel Comments Regarding EPA's Risk Management of Methylene Chloride Under TSCA

Dear Ms. Feustel:

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to submit comments, as a small entity representative (SER), on U.S. EPA's development of risk management regulations for methylene chloride (MCL) under the Toxic Substances Control Act (TSCA).

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture innovative chemistries used in a wide range of commercial, industrial and consumer products. Over 70% of SOCMA's membership are small businesses; SOCMA is therefore acting as a SER to advocate on behalf of its members in EPA's Small Business Advocacy Review (SBAR) Pre-Panel review of MCL.

SOCMA has a vital interest in ensuring the risk management actions taken by EPA account for the significant economic impact on its members who use MCL in their chemical manufacturing operations. SOCMA also has an interest in ensuring that TSCA risk management properly accounts for existing regulations that mitigate the risks associated with MCL's conditions of use.

In these comments, we:

1. Briefly summarize the separate responses submitted by two member company SERs;
2. Describe two significant legal shortcomings of the final risk evaluation that could jeopardize the final risk management rule: the evaluation's use of "catch-all" condition of use categories, and its failure to incorporate monitoring data submitted by SOCMA; and

3. Discuss two important regulatory issues for the risk management rule: the merits of an exclusion for closed systems, and the need for EPA to articulate how the risk management rule will interact with the OSHA methylene chloride standard (and other OSHA rules).

I. Workplace Conditions of Use and Exposures

As part of these comments, SOCMA has included information from two member companies who are participating as SERs in the SBAR process. Both companies use methylene chloride as a processing aid (a condition of use categorized under Group 5). Each company has provided responses to EPA's questionnaire, relevant exposure data, and diagrams of their specific manufacturing processes. We would also like to summarize each companies' circumstances briefly:

VanDeMark Chemical uses MCL as a reaction medium in a closed system for the production of polycarbonates. The substance is not consumed or incorporated into any chemical formulation; it is recycled and re-used in the system each time the company runs a batch. Therefore, the only points of exposure are when MCL is introduced into the system, or during line breaks. Introduction of MCL is conducted mechanically with a vaporized pressure tank. Line breaks occur after the system has been purged with nitrogen. Employees also utilize PPE as a secondary safety measure, though engineering controls are the primary mechanism that controls exposure. Monitoring data demonstrates that ambient air exposures are far below the OSHA Permissible Exposure Limit (PEL) and action level. MCL is an ideal solvent for the company's manufacturing process due to its high vapor pressure and low boiling point, while other alternative solvents have higher risk profiles, making substitution an unlikely prospect for VanDeMark's specific chemical manufacturing process.

Halocarbon uses MCL as a heat transfer fluid in a closed system for the production of pharmaceuticals, intermediates, and other industrial chemicals. The chemical performs as a heat transfer fluid and is not reacted during manufacturing. As with VanDeMark, the only points of exposure to the substance are from introduction into the system and from line breaks during routine maintenance. For line breaks, the substance is mechanically cleared from the system beforehand using pressurized nitrogen, with employees utilizing appropriate PPE. Monitoring data shows exposure points are well below the OSHA PEL and action level. The company's manufacturing process was uniquely engineered around the use of MCL as a heat transfer fluid, and would require a full plant redesign with attendant shutdown time if MCL can no longer be used. Alternative substances are also unavailable, as other heat transfer fluids lack the necessary physical properties for the prescribed process conditions and have other problematic environmental risk attributes.

II. Shortcomings of the MCL Risk Evaluation

As EPA proceeds with risk management of MCL, shortcomings in the risk evaluation have become increasingly evident. Left unaddressed, these issues could end up undermining the legal validity of the final risk management rule.

A. EPA's Use of "Catch-All" Categories in the Risk Evaluation

Both of the SOCMA member SERs are classified in the "processing aid not otherwise listed" category of industrial and commercial uses (Group 5, under the SBAR process). For this category, EPA has made an unreasonable risk determination on a broad category of uses without information that meaningfully resembles those uses in practice.

Until EPA has evaluated a COU, the statute establishes no default presumption about its risk status: the COU could pose unreasonable risk, or not. Either outcome can only be reached after EPA undertakes an evaluation of the COU. It is certainly clear that an *unreasonable* risk determination requires compliance with statutory requirements (see TSCA §§ 6(a) and 6(b)(4)(F)). It is improper for EPA to include a catchall category of uses “not otherwise listed” in its risk evaluations, since EPA would, by definition, not even have identified what those COUs are or have evaluated them. This is particularly glaring in regard to Halocarbon’s use of MCL as a heat transfer fluid - a use that EPA did not even contemplate during the risk evaluation process - yet which has now been categorized as posing unreasonable risk.

B. EPA’s Failure to Use Monitoring Data Submitted to it in Comments

While SOCMA recognizes that EPA must base its risk evaluation on what data and information is available to it during the risk evaluation, SOCMA and its member SERs did in fact provide EPA with relevant exposure data for the draft risk evaluation in their comments on the draft risk evaluation. SOCMA supplied EPA with recent workplace air monitoring data on use of MCL as a reaction medium from two companies, VanDeMark Chemical and a manufacturer of active pharmaceutical ingredients (APIs). Halocarbon also supplied exposure data via the Halogenated Solvents Industry Association (HSIA). The data collectively was representative of current uses of MCL as a solvent or heat transfer fluid in a closed-loop manufacturing process, whether it be for pharmaceuticals, intermediates, or other specialty chemicals. The risk evaluation confirms that EPA ignored this information when finalizing the risk evaluation. Its Response-to-Comments (RTC) document states that EPA did not consider this data because it removed pharmaceutical production from the risk evaluation under the applicable TSCA exclusion.¹ Regardless of the exclusion, the data was useful for understanding air exposures from facilities in the “processing aid” category, or that would have fallen into the category if they did not exclusively manufacture pharmaceuticals.

The RTC document also points back to a section of the final risk evaluation that says that EPA based all of its air monitoring analysis on data from governmental monitoring or published literature. It says nothing about data supplied in comments.² The document does discuss however, that EPA evaluated MCL air data pre-and post- OSHA MCL standard and decided that, since concentrations only dropped 31-35% after the PEL dropped 90%, they may as well amass the data together to get “a more robust data set” – in effect creating a data set with higher values.³ Problematically, this portion of the risk evaluation concludes by saying:

EPA has sought additional data regarding exposures, particularly during the public comment phases on the documents preceding the draft version of this risk evaluation (e.g., the methylene chloride Section 6 rule and the problem formulation). With the exception of paint and coating removers, *EPA has not received information to date to indicate that workplace changes have occurred broadly in particular sectors over the past 40 years.*⁴

SOCMA is disappointed by the Agency’s disregard of exposure data provided by these companies, which represented a transparent and earnest effort to accurately characterize their COU and improve the risk

¹ RTC, pgs. 73-74.

² RTC, pgs. 78-79.

³ See Risk Evaluation at pg. 123.

⁴ Id. at 125.

evaluation. TSCA requires EPA, in conducting risk evaluations, to “use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information *are reasonable for* and consistent with the intended use of the information; [and] (2) the extent to which the information *is relevant for* the Administrator's use in making a decision about a chemical substance or mixture. . . .”⁵ The monitoring data supplied by SOCMA and its member companies is the best and most currently available technical information for the purposes of evaluating risk from use of MCL as a processing aid, and is the most reasonable and relevant data for estimating workplace exposures at that category of facilities.

The data submitted by SOCMA and its members is vastly more reasonable, relevant, and newer, than the information which EPA used when it found unreasonable risk for the entire category of processing aid use. The MCL risk evaluation used exposures from the production of cellulose triacetate film as the sole proxy for all of the exposures falling into this broad processing aid category. EPA lists four studies to estimate exposure from this process, one study from 1983 and three from 1999. All of these studies thus predated the compliance date of the 1997 OSHA MCL Standard (2000), and two of them involve non-U.S. workplaces. Collectively, these studies contained over 166 samples, with a central tendency 8-hr TWA of 1,000 mg/m³ – almost 12 times the PEL – and a high-end 8-hr TWA of 1,400 mg/3. EPA obliquely acknowledges the limitations of this data in the risk evaluation, noting that “uncertainties in the analysis include the representativeness of the monitoring data toward the true distribution of inhalation concentrations for the industries and sites using methylene chloride as processing aid.”⁶ As can be seen, however, EPA was in knowing possession of far more representative data than it used. This problematic outcome has effectively pulled SOCMA’s members into risk management when their COU, processing conditions, and workplace exposures are not remotely representative of the modeling and data EPA utilized when it found unreasonable risk from the processing aid category. It would be arbitrary and capricious for EPA to impose risk management requirements on these companies on this basis.⁷

III. Regulatory Options for the Use of MCL as a Processing Aid

EPA has at least two ways to substantially ameliorate the burden of any risk management requirements that it imposes on SOCMA’s members.

A. EPA Should Provide for a Regulatory Exclusion for Closed Systems

One of the principal questions that the SBAR Panel asks of its SERs is to identify “any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.”⁸ When issuing its risk management rule, EPA should provide for an exclusion for the use of MCL as a processing aid in a closed system. Both SOCMA members utilize MCL in closed systems with very minimal exposures, as

⁵ 15 U.S.C. § 2625(h) (emphasis added).

⁶ Risk Evaluation at pg. 492.

⁷ An alternative approach would be for EPA to revise the final risk evaluation in parallel with its promulgation of the risk management rule to correct these and any other flaws. While it is not legally required to do so, EPA could seek comment on its proposed revisions to the risk evaluation at the same time it sought comments on the proposed risk management rule. It could then finalize both of them together.

⁸ 5 U.S.C. § 603(c).

demonstrated by their documented sampling data. EPA anticipated just such an exclusion when it promulgated the risk evaluation framework rule. The preamble to that rule states:

EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only 'de minimis' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate.⁹

While EPA may have legal or technical misgivings about categorically excluding such processes from a risk evaluation, and it should have no misgivings about excluding such 'de minimis' exposures from risk management.

B. EPA Should Properly Account for Applicable OSHA Requirements

The other principal question that the SBAR Panel asks of its SERs is to identify "all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule."¹⁰ EPA has not yet articulated how its risk management rules, which will likely be focused on worker protection, will align with, account for, or avoid duplication with OSHA standards. SOCMA strongly urges EPA to address this matter at length in its MCL risk management proposal.

SOCMA urges EPA, in its risk management rules, either to adopt relevant OSHA requirements or to confirm that compliance with such requirements would satisfy a comparable risk management requirement, whenever possible. This approach has precedent in EPA's Risk Management Plan (RMP) rule, which aligns its process hazard analysis (PHA) requirements with the OSHA Process Safety Management (PSM) standard, its safety information requirements with the OSHA Hazard Communication standard, and its fire prevention and protection requirements with the OSHA Welding, Cutting & Brazing standards.¹¹

EPA should also consider letting entities comply with either an Existing Chemical Exposure Limit (ECEL) or exposure control work practices to satisfy the requirements of a risk management regulation. If EPA concludes that an ECEL must be instituted in a manner lower than the OSHA PEL, it should align its requirements with the MCL standard, but with the lower threshold replacing the OSHA 25ppm limit. It should also provide optional engineering and work practice control methods in lieu of the ECEL, which entities could choose to implement to adequately mitigate exposure. This two-pronged approach has strong precedent under OSHA's Respiratory Crystalline Silica (RCS) Standard, which provides that construction employers can either use a control method laid out in Table 1 of the standard, or they can measure workers' exposure to silica and independently decide which controls work best to limit exposures in their workplaces to the PEL.¹²

As discussed in the addendum that follows, VanDeMark and Halocarbon both use engineering controls, administrative controls, and PPE to reduce MCL exposures to levels well below the OSHA PEL (and the action level). EPA should adopt a risk management rule that recognizes when regulated entities use these

⁹ 82 FR 33726, 33729 (July 20, 2017).

¹⁰ 5 U.S.C. § 603(b)(5).

¹¹ See 40 C.F.R. § 68.67 (a), (f), § 68.48(a)(1), § 68.65, § 68.85(b).

¹² 29 C.F.R. § 1926.1153(c), (d).

advanced workplace safety practices. SOCMA prefers that, if necessary, EPA specify a performance standard that is both flexible and straightforward to implement, rather than imposing prescriptive requirements for particular types of control technology.

Conclusion

SOCMA appreciates the opportunity to comment on EPA's risk management of methylene chloride. We look forward to continued involvement and collaboration with EPA on this and other TSCA regulatory efforts. If you have any questions about these comments, please feel free to contact me at jrothstein@socma.org or 571-348-5122.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jared Rothstein", with a stylized flourish at the end.

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